

#### US006200773B1

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### (54) DIAGNOSTICS BASED ON TETRAZOLIUM COMPOUNDS

## (75) Inventors: **Tianmei Ouyang**, Milpitas; **Yeung Siu Yu**, Pleasanton, both of CA (US)

#### (73) Assignee: Lifescan, Inc., Milpitas, CA (US)

### (\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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#### Related U.S. Application Data

- (63) Continuation-in-part of application No. 09/161,876, filed on Sep. 28, 1998, now Pat. No. 5,902,731.
- (51) **Int. Cl.**<sup>7</sup> ...... **C12Q 1/32**; C12M 1/40

#### (56) References Cited

#### U.S. PATENT DOCUMENTS

	5,298,144		anba et al
5,510,245 4/1996 Magers		50,595 11/1994 Be 10,245 4/1996 Ma	ell et al

#### FOREIGN PATENT DOCUMENTS

0 638 805 A2 2/1995 (EP) ...... G01N/33/52

#### OTHER PUBLICATIONS

*Tietz Textbook of Clinical Chemistry*, 2nd Ed., ed. by C. Burtis et al., W.B. Saunders Co., Philadelphia, PA, 1994, pp. 974–978 and 1174–1175.

KetoSite© test (available from GDS Diagnostics, Elkhart, IN.) Dec. 29, 1993.

Hemoglobin: Molecular, Genetic and Clinical Aspects, by Franklin H.Gunn and Bernard G. Forget, W.B. Saunders Co., Philadelphia, PA, 1968, pp. 638–644.

Glucometer Encore™ Blood Glucose Test Strips, Distributed by Miles Canada, Inc., Diagnostics Division, Etobicoke, Ontario M9W 1G6, 1992.

\* cited by examiner

Primary Examiner—Ralph Gitomer
Assistant Examiner—Marjorie A. Moran
(74) Attorney, Agent, or Firm—James Riesenfeld

#### (57) ABSTRACT

A reagent is suitable for measuring the concentration of an analyte in a hemoglobin-containing biological fluid, such as whole blood. The reagent comprises dehydrogenase enzyme that has specificity for the analyte, NAD, an NAD derivative, pyrrolo-quinoline quinone (PQQ), or a PQQ derivative, a tetrazolium dye precursor, a diaphorase enzyme or an analog thereof, and a nitrite salt. The reagent causes dye formation that is a measure of the analyte concentration. The nitrite salt suppresses interfering dye formation caused non-enzymatically by the hemoglobin. Preferably, the reagent is used in a dry strip for measuring ketone bodies, such as beta-hydroxybutyrate.

#### 14 Claims, 4 Drawing Sheets

